

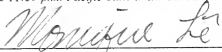
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/NN/ 08/27/2008 (08/27/2008)

PATENT

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Monique X. Le

Applicant : J. Christopher Marmo Confirmation No. 1370

Application No. : 10/811,690

Filed : March 29, 2004

Title : HYDROGEL CONTACT LENSES AND PACKAGE SYSTEMS
AND PRODUCTION METHODS FOR SAME

Grp./Div. : 1796

Examiner : Nathan M. Nutter

Docket No. : 1128-01-PA-TD

Customer No. : 79567

REPLY BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

43 Corporate Park, Suite 204
Irvine, California 92606
August 8, 2008

Commissioner:

This is a reply brief in response to the Examiner's Answer mailed on July 10, 2008.

Appellants maintain the arguments stated in the appeal brief. Appellants further clarify some of the arguments below.

Real Party in Interest - Update:

From between the time Appellant filed its brief on June 3, 2008 and now, the present application has been assigned to CooperVision International Holding Company, LP and recorded at REEL/FRAME 021325/0448.

I. ERROR IN REJECTION UNDER 35 U.S.C. § 103 BECAUSE REFERENCES DO NOT TEACH OR SUGGEST ALL THE ELEMENTS OF THE CLAIMS ON APPEAL

To establish a prima facie case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (MPEP §2142).

1. §103(a) rejection of claims 172-178 and 186 as unpatentable over Hu et al., Gordon, or Shah, each taken in view of Krezanoski et al.

In rejecting the above-referenced claims, the Examiner maintained:

. . .The references employ each of the constituents/components in identical fashion as recited herein. The argument that the 'cited references taken alone or in any combination do not teach or suggest a package system' . . . that include the recited contact lens, the recited sterile packaging liquid medium, wherein both the contact lens and the sterile packaging liquid medium comprise . . .a polyalkylene glycol[] ignores the teaching of the references. . . The primary references teach the contact lens of the claims. The secondary references show the solutions for cleaning/storage and show such as conventional, as recited herein. . . (Examiner's Answer, pages 7-8)

Claim 172 recites a package system comprising: a single use disposable hydrogel contact lens ready for use in an eye and comprising a cast molded contact lens body comprising a hydrophilic polymeric material and a water soluble polymer component; a sterile packaging liquid medium comprising an amount of the water soluble polymer component in addition to that present in the contact lens body; and a container holding the contact lens and the sterile packaging liquid medium, wherein the water soluble polymer component of the cast molded contact lens body and of the sterile packaging liquid medium comprises a polyalkylene glycol. (Underlining added).

Appellant is unable to find any teaching in the cited references, alone or in combination, of a package system wherein both "the water soluble polymer component of the cast molded contact lens body and of the sterile packaging liquid medium comprises a polyalkylene glycol", as recited in claim 172. To date, the Examiner has not provided any specific reference to column, line number, or paragraph to any of the references, either alone or in combination, to support his position, despite appellant's request to do so.

As the comments further below will clarify, the Examiner relied on Hu, Gordon, or Shah (the "primary references") to each disclose a contact lens incorporating a polyalkylene glycol polymer or a polyethylene glycol polymer and on Krezanoski to teach a packaging solution comprising the same polyalkylene glycol or polyethylene glycol polymer. However, none of the references teaches the claimed elements; and the citation to the lines and paragraphs relied by on the Examiner are directed to something else. Thus, and among other things, the cited combinations of references fail to disclose each and every element and limitation of the rejected claims. As such, a prima facie case of obviousness has not been established.

The first set of primary references will now be discussed individually and in combination with Krezanoski.

In the "Response to Argument" section of the Examiner's Answer, the Examiner states:

...Regarding Hu et al., the reference shows the use of polyethylene glycol in the hydrophilic contact lens, at paragraph [0029], as previously pointed out. Gordon shows the same at the paragraph bridging column 5 to column 6. Shah teaches the use at the paragraph bridging column 3 to 4. No specific polyalkylene glycol is recited in claim 172. (Examiner's Answer, page 8)

Paragraph [0029] of the Hu reference is reproduced in full below:

[0029] Objects of the present invention are achieved through formation of hydrophilic hydrogel contact lens using, for instance, monomers such as unsaturated alkyl (meth)acrylate or its derivatives, preferably 2-hydroxyethyl methacrylate (HEMA); optionally a vinyl containing comonomer(s), preferably methacrylic acid (MM), N-vinylpyrrolidone (NVP), or polyethylene(400) glycol (PEG 400) monomethyl ether monomethacrylate; crosslinking agents, preferably polyethylene glycol dimethacrylate in a molecular weight range from 400 to 1000; initiators, preferably 2,2'-azobisisobutyronitrile (AIBN), 2-hydroxy-2-methyl-1-phenyl-1-propanone (DAROCUR, RTM. 1173, E. Merck, Darmstadt, Germany), and 1,1'-azodi(hexahydrobenzotriazole); and optional additives, preferably 2-hydroxy-4-acryloyloxyethoxybenzophenone as a UV blocking agent and copper phthalocyanine blue as a handling colorant; in the presence of an IPN

agent, preferably polyvinylpyrrolidone (PVP) or poly-2-ethyl-2-oxazoline (PEOX), wherein polymerization of monomers occurs through E-beam, ultraviolet, and/or thermal curing processes (emphasis added).

Appellant submits that nowhere in paragraph [0029] is disclosed the composition polyalkylene glycol or polyethylene glycol in the contact lens. Contrariwise, Hu et al. teaches the use of "polyethylene (400) glycol (PEG 400) monomethyl ether monomethacrylate" or "polyethylene glycol dimethacrylate", which are esters formed from polyethylene glycol and which are chemically distinct from polyethylene glycol and polyalkylene glycol. As an analogy, Appellant is pointing out that H_2O is not the same as $H_2 + \text{Oxygen}$.

As for the next primary reference, Gordon, the Examiner points to the "Abstract, column 2 (lines 38-55), column 3 (line 64) to column 6 (line 63), [and] the Example at columns 8 and 9 and the claims" to allegedly disclose the claimed limitations (Examiner's Answer, Page 4). The Abstract is reproduced from the Gordon reference as follows:

Contact lens of a hydrogel composition containing a physiologically acceptable aqueous solution and water-insoluble but water-swellaible polymer composition from:

(A) a water-soluble polymer of a heterocyclic N-vinyl polymerizable compound containing carbonyl functionality adjacent to nitrogen in the ring; and

(B) a polymerizable mixture containing:

- (1) polymerizable monoester of acrylic and/or methacrylic acid and polyhydric alcohol;
- (2) an alkyl acrylate and/or alkyl methacrylate and/or vinyl ester;
- (3) divinyl benzene and/or divinyl toluene.

(ABSTRACT, emphasis added)

Clearly, the Abstract does not disclose a lens made from a polyalkylene glycol or a polyethylene glycol. Thus, it does not support the Examiner's position.

Col. 2, lines 38-55, is similar to the Abstract and therefore is not applicable.

As for column 3, line 64 to column 6, line 63, the broad range given by the Examiner as support is not helpful and may appear to be in violation of 35 U.S.C. §132, which requires a well articulated and reasoned Office Action so that an applicant may be properly notified of the reasons for the rejection of the claim so that he or she can then decide how best to proceed. Notwithstanding the deficiency, a review of the text shows the following about the monoester of acrylic and/or methacrylic and polyhydric alcohol:

Such polymerizable monoesters are monoesters of either acrylic and/or methacrylic acid and a polyhydric alcohol and preferably a dihydric alcohol. Suitable dihydric alcohols which may be employed to form the esters used in the present invention include among others ethylene glycol, 1,3-propanediol, the dialkylene glycols such as diethylene glycol and dipropylene glycol; and the polyalkylene glycols such as polyethylene glycol and polypropylene glycol; 1,6-hexamethylene glycol... (Col. 5, lines 50-62, emphasis added)

Thus, Gordon teaches the use of monomers which are esters formed from a polyhydric alcohol and preferably from a dihydric alcohol, which includes polyalkylene glycols such as polyethylene glycol. Again, Appellant submits that esters that are formed from polyethylene glycol and acrylic acid or methacrylic acid are NOT polyethylene glycol, and more broadly they are not in the class of polyalkylene glycol.

As for the Shah reference, the Examiner points to the "Abstract, column 2 (line 1) to column 4 (line 49), [and] the many Examples and the claims" to provide support (Page 4, Examiner's Answer). Again, the broad range given without more does not adequately apprise Appellant of the grounds for rejecting the claims. However, in reviewing the cited text in question, Shah appears to teach:

The copolymerizable monomers with which the N-vinyl lactams can be copolymerized to form copolymers containing 10 to 99, preferably 25 to 99, mole percent N-vinyl lactam and correspondingly 1 to 90, preferably 1 to 75, mole percent of comonomer, include N,N-dimethyl acrylamide, glyceryl methacrylate, diethylene or triethylene glycol monomethacrylate or other hydrophilic monomers, as well as vinyl acetate, alkyl acrylate or methacrylate, vinyl alkyl ethers, acrylonitrile, vinyl chloride, or other hydrophobic monomers (Col. 4, lines 2-14, emphasis added).

Thus, Shah teaches the use of diethylene or triethylene glycol monomethacrylate in the disclosed contact lenses, which is an ester formed from diethylene or triethylene glycol with monomethacrylic acid. Again, Appellant respectfully submits that an ester formed from diethylene or triethylene glycol is NOT a polyalkylene glycol.

In summary, all three primary references, either alone or in combination, fail to disclose a single use disposable contact lens comprising a polyalkylene glycol polymer, such as by providing a polyalkylene glycol polymer in the composition that is polymerized to form the contact lens. The three references instead all teach an ester of a composition, which is not the

same as the composition of the claimed package system comprising a contact lens having a specific polymer.

The Examiner relies on Krezanoski et al. to teach a packaging solution. The '644 Krezanoski patent discloses a cleaning solution comprising polyoxypropylene-polyoxyethylene block copolymers with very specific characteristics, including: "a molecular weight between about 1900 and 15,500, and a water solubility in the excess of about 10 grams per 100ml, a cloud point in 1 percent aqueous solution above about 30C, and a Foam Height in excess of 30 mm. . ." (Abstract; See also Col. 8, lines 29-42). The referenced cleaning solution further contains a sufficient amount of a germicidal composition, a sufficient amount of salt (Col. 4, lines 33-34), and a viscosity builder such as hydroxyethyl cellulose (Col. 4, lines 40-42). The polyoxypropylene-polyoxyethylene block copolymers satisfying the above-referenced conditions are commercially available under the trademark "Pluronic", which are classified as nonionic surface-active agents (Col. 8, line 28). The purpose of the polyoxypropylene-polyoxyethylene block copolymers is to:

...effectively remove proteins, fats, and the mucopolysaccharides that accumulate on the silicone lens surfaces when they come in contact with body tissues and fluids. The block copolymers also act to help maintain the germicidal storage container in a generally clean state. Importantly, the block copolymers also act as a wetting agent in the solution so that the flexible silicone contact lenses can be immediately inserted in the eye of the user upon their removal from the solution without using a separate wetting solution. (Col. 9, lines 21-30).

Thus, the Krezanoski reference fails to provide the deficiencies in Hu, Gordon and Shah by teaching the use of polyalkylene glycol or polyethylene glycol in a hydrogel contact lens instead out of esters of a polymer compound. Additionally, Krezanoski fails to disclose a packaging system comprising a sterile packaging solution comprising an amount of the water soluble polymer component in addition to that present in the contact lens body; wherein the water soluble polymer component comprises a polyalkylene glycol, as recited in part by claim 172, or polyethylene glycol as recited in claim 186.

In combining the primary references and Krezanoski, the Examiner goes so far as to say that:

...the use of the solutions for cleaning/storage with the contact lenses of either primary reference would have been a prima facie obvious modification, as being standard in the art. Contact lenses, especially hydrophilic lenses, are stored in liquid to prevent their drying out and becoming brittle and useless. The employment of a package is notoriously obvious since the product must be vended and distributed, or stored prior to distribution. (Page 5, Examiner's Answer).

The Examiner's statements fly in the face of warnings and cautions noted by Krezanoski against arbitrarily combining contact lenses with commercially available cleaning, storing, and wetting solutions. The following excerpts from the '644 Krezanoski reference are representative:

In testing the commercially available solutions designed for conventional hard polymethylmethacrylate contact lenses, it has been found that they are not adequate and in some instances detrimental to the successful use of flexible silicone contact lenses. For example, it has been found that polyvinyl alcohol, the wetting ingredient in many wetting solutions for conventional hard polymethylmethacrylate lenses, is not an effective wetting agent for silicone lenses. It has also been found that the preservative chlorobutanol present in many commercially available solutions designed for hard polymethylmethacrylate lenses is absorbed and concentrated by silicone lenses. This ability of the silicone elastomer to concentrate chlorobutanol could ultimately change the physical and chemical properties of the lenses to make them ineffective in providing visual correction. (Col. 2, lines 1-17, emphasis added).

Moreover, patients experimentally wearing flexible silicone rubber lenses stored in a chlorobutanol containing storage solution have complained of discomfort. This was found to be directly associated with the high concentrations of chlorobutanol in the silicone lenses thus treated. (Col. 2, lines 18-23, emphasis added).

The highly hydrophobic nature of the silicone elastomer has prevented their uniform and effective cleaning and wetting by all available conventional cleaners and wetting agents. Thus, various generic classes of organic compounds have been screened including cellulose derived gums, polyvinylpyrrolidone polymers, polyvinyl alcohol with varying degrees of acetylation, polysaccharides, lanolin derived nonionic surfactants, ethoxylated sorbitol anhydrides, and various cationic, anionic and nonionic detergents, but to date none have been found acceptable. (Col. 2, lines 24-34, emphasis added).

Soft contact lenses of the hydrated gel type have a number of properties which complicate their effective care. For example, the hydrophilic OH groups of the lenses attract and hold large amounts of water in the plastic, and this leads to difficulties in cleaning and sterilizing the lenses. Further difficulties in caring for hydrated gel lenses occur because these lenses complex and concentrate chlorobutanol, benzalkonium chloride, thimerosal, phenylmercuric nitrate and other preservatives found in solutions for conventional lenses. Generally, these preservatives are inactivated in the complexed state. Also, if concentrated preservatives are released too rapidly at the cornea, they may cause chemical burns. Thus, solutions and cleaners now available for conventional hard lenses cannot be used with gel lenses. (Col. 2, line 64 to Col. 3, line 11, emphasis added).

Thus, statements made by Krezanoski support the general proposition that in cases involving chemical compounds, such as a reaction between a hydrophilic soft contact lens that can absorb and react with components of a contact lens cleaning solution, "it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed [lens and solution combination]." (*Takeda Chemical Industries, Ltd. V. Alphapharm Pty., Ltd.*, 492 F. 3d 1350, 1357 (Fed. Cir. 2007)).

Indeed, the Examiner's approach has thus far been limited to finding prior art references that teach soft contact lenses and a prior art that teaches a cleaning and storing solution and combining them in an attempt to render the rejected claims obvious without compensating for reaction, absorption, and compatibility between highly absorbent soft contact lenses and commercially available packaging solutions. However, this approach ignores the warnings sounded by Krezanoski, that even in the specific field of contact lens cleaning solutions, not all commercially available cleaning and storing solutions are appropriate for soft contact lenses, which contradicts the Examiner's assertion that using any soft contact lenses with any commercially available cleaning, wetting, and storing solutions as "being standard in the art" and "notoriously obvious" (Page 5, Examiner's Answer). The latter comment clearly violates many tenets of sound operating practice, namely that: (1) the contact lens package be ophthalmically safe and generally suitable and appropriate for direct placement on the eye without rinsing, (2) the product does not expose the company to unnecessary and unpredictable product liabilities, and (3) the product is manufacturable in a cost effective manner. The Examiner's random

shotgun approach would violate all three tenets. Random combination would drive up costs as some combination will be harmful and unsafe and therefore costly to experiment. In addition, not only would a person of ordinary skill in the art not simply substitute individual components among different contact lens cleaning solutions, but furthermore, as discussed in appellant's Appeal Brief, a person of ordinary skill in the art would not simply substitute components from a contact lens cleaning solution, or modify the teachings of a reference for a contact lens cleaning solution, in providing a contact lens packaging solution which must meet stringent regulatory guidelines.

Indeed, in view of the express teachings of Krezanoski, appellant submits that Krezanoski teaches away from the assertion proposed by the Examiner in maintaining the rejection and teaches away from the present claims. "As a general rule, references that teach away cannot serve to create a prima facie case of obviousness." (*McGinley v. Franklin Sports, Inc.* CAFC 8/21/01 citing *In re Gurley*, 31 USPQ2d 1131, (Fed. Cir. 1994)). In this case, the primary reference relied upon by the Examiner teaches away from the present claims, and therefore, the rejection under 35 U.S.C. 103(a) over the combination of references cannot be properly maintained.

As set forth in the Appellant's Brief, the claimed package system solves a problem that was not previously recognized, namely to provide a contact lens that will leach less of its ingredients which provide beneficial properties over time due to the presence of the same ingredient in the lens composition as package solution, which results in a lower concentration gradient between the contact lens and the package solution to yield a lower loss of the ingredient in the lens. Not only has the Examiner failed to identify any prior art that recognizes migration as a problem, none of the cited references, either alone or in combination, teaches the claimed combination in which the lens and the packaging solution has the same water soluble polymer component, let alone a combination that solves such a problem or a combination with polyalkylene glycol or polyethylene glycol.

Again, independent claim 172 recites, in part, a package system comprising a contact lens in a package with a packaging solution that has the same water soluble polymer component in addition to that present in the contact lens body. The Examiner's Final Office Action amounts to rejecting the claims based on references that: (1) do not teach, suggest, or motivate a person of

ordinary skill in the art to combine in the manner suggested (as frowned upon by Krezanoski and as required by the Takeda decision). (2) do not teach a resultant product wherein a packaging solution and the contact lens body have the same water soluble polymer component, and (3) do not teach a package system with a packaging solution that has the same polyalkylene glycol or polyethylene glycol in addition to that present in the contact lens body. The Examiner's Final Office Action amounts to rejecting the claims based on references that produce a combination having a contact lens made from an ester of a chemical compound (i.e., the primary references) and a packaging solution made of polyoxypropylene-polyoxyethylene block copolymers with very specific characteristics (i.e., Krezanoski), including a molecular weight between about 1900 and 15,500, and a water solubility in the excess of about 10 grams per 100ml, a cloud point in 1 percent aqueous solution above about 30° C. and a Foam Height in excess of 30 mm. By looking at the combination of references compared to the claimed package system, ". . .the claimed subject matter as a whole would [NOT] have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains" (35 U.S.C. §103(a)).

As the cited references, either individually or as a combination, fail to teach or suggest the inclusion of a polyalkylene glycol in the contact lens body, inevitably they also fail to disclose the limitation of the cast molded contact lens AND a packaging liquid medium comprising the SAME water soluble polymer component, and the water soluble polymer component of the cast molded contact lens body and of the sterile packaging liquid medium comprises a polyalkylene glycol.

In view of the foregoing, Appellant respectfully submits that the Examiner failed to establish a prima facie case of obviousness, and claim 172 is patentable for at least this reason. As claims 173-178 and 186 depend from claim 172, they too should be allowable for the same reason.

2. §103(a) rejection of claims 172-178 and 186 as unpatentable over Tanaka et al. or Salpekar, each taken in view of Krezanoski et al.

In rejecting the above-identified claims, the Examiner states:

The reference to Tanaka et al (U.S. 6,008,170) shows the contemplated contact lens in the instant claims at the Abstract, the paragraph bridging column 3 to column 4, column 6 (lines 45-61), the Examples and claims. (Examiner's Answer, page 6)

Appellant respectfully reiterates that the '170 Tanaka reference does not show the contemplated contact lens in the claimed package system. Accordingly, even if Krezanoski discloses a package solution as claimed, a position that Appellant continues to oppose, the combination is still defective. Instead, Tanaka discloses a contact lens cleaning solution and methods for cleaning contact lenses using the same (See, e.g., the title, the Abstract, and the specification).

As the following citations will clearly show, the '170 Tanaka reference does not show the contemplated contact lens in the claimed package system. In the paragraph bridging column 3 to column 4, Tanaka does NOT disclose a contact lens, but instead, Tanaka specifically discloses a cleaning solution containing an additional thickener:

In a further preferred form of the contact lens cleaning solution of the present invention, the cleaning solution further contains as an additional component a thickener such that an aqueous solution which contains only said thickener at the same concentration as a concentration of said thickener in said cleaning solution gives surface tension of not lower than 50 dyn/cm at ordinary temperature. The thickener is advantageously selected from the group consisting of: polyvinyl pyrrolidone, copolymer of methoxyethylene and maleic anhydride, xanthan gum, and hydroxyethyl cellulose. (Col. 3, line 62 to Col. 4, line 5).

Others citations referred to by the Examiner in the '170 Tanaka patent (i.e., Abstract, Col. 6, lines 45-61, the Examples and claims) also disclose primarily a cleaning solution, as evident in the following paragraph (Col. 6, lines 45-61).

To the present contact lens cleaning solution, there is further added a suitable thickener so as to give a suitable degree of viscosity to the cleaning solution, improve the touch of the cleaning solution and enhance a cleaning effect with respect to the lipid deposits. As the thickener to be added to the present cleaning solution, polyvinyl pyrrolidone, copolymer of methoxyethylene and maleic anhydride, xanthan gum or hydroxyethyl cellulose is preferably used. The cleaning solution contains as an additional component a thickener such that an aqueous solution which contains only the thickener at the same concentration as a concentration of the thickener in the cleaning solution gives surface tension of not lower than 50 dyn/cm at ordinary temperature. Accordingly, the addition of the thickener is effective to adjust the viscosity of the cleaning solution to a suitable

value without adversely influencing the action of the gum arabic to render the contact lens surface hydrophilic.

Similarly, the Examples and the claims are all directed to a cleaning solution. Thus, Appellant vigorously disputes the Examiner's statement that the reference to Tanaka et al. "shows the contemplated lens employed in the instant claims". By combining Tanaka and Krezanoski, the Examiner rejects appellant's claimed package system based on the combination of a cleaning solution containing a thickener and another cleaning solution containing polyoxypropylene-polyoxyethylene block copolymers without a contact lens. Thus, Appellant submits that the Examiner's rejection is clearly unsubstantiated and rescission of the rejection is respectfully solicited.

With respect to the disclosures of Salpekar et al, the Examiner points to several sections of the specification to show the "contemplated contact lens employed in the instant claims", such as the Abstract, column 3 (line 53) to column 7 (line 57) and the claims. The Abstract of Salpekar clearly states:

The present invention is directed to new and improved solutions for packaging contact lenses and to methods for treating contact lenses with such solutions to improve the comfort of the lenses during wear".

While Salpekar et al. does disclose hydrogel contact lenses, the essence of Salpekar's invention has to do with packaging solutions and the effect of the disclosed packaging solutions on different contact lenses. Nowhere in the '366 Salpekar patent are disclosed cast molded contact lenses comprising a water soluble polymer component which is a polyalkylene glycol. Thus, Appellant disagrees with the Examiner's assertion that "[t]he reference to Salpekar et al (US 6,440,366) shows the contemplated lens recited in the instant claims".

The Examiner relies on Krezanoski et al. to disclose a cleaning solution. As set forth above, not only does the Krezanoski patent fail to provide the deficiencies apparent in the '366 Salpekar patent, it also fails to disclose a packaging system comprising a sterile packaging solution comprising an amount of the water soluble polymer component in addition to that

present in the contact lens body; wherein the water soluble polymer component comprises a polyalkylene glycol, as recited in part by claim 172.

As the cited references, either individually or as a combination, fail to teach or suggest the inclusion of polyalkylene glycols in the contact lens body, inevitably they also fail to disclose the limitation of the cast molded contact lens AND the packaging liquid medium comprising the SAME water soluble polymer component, and the water soluble polymer component of the cast molded contact lens body and of the sterile packaging liquid medium comprises a polyalkylene glycol.

In view of the foregoing, Appellant respectfully submits that the Examiner failed to establish a *prima facie* case of obviousness, and claim 172 is patentable for at least this reason. As claims 173-178 and 186 depend from claim 172, they too should be allowable for the same reasons.

II. ERROR IN REJECTION UNDER 35 U.S.C. § 103 BECAUSE NO MOTIVATION TO MODIFY/COMBINE CITED REFERENCES

Not only do the cited references, either individually and in any permissible combination, fail to disclose all the elements and limitations of the pending claims, Appellant further submits that contrary to the Examiner's assertion, a person of ordinary skill in the art would not be motivated to modify the cited references or combine the teachings of the cited references to come up with the claimed package system. "In cases involving new chemical compounds, [such as in this case where a new package system comprising a lens body comprising a combination hydrophilic polymeric material and a water soluble polymer component comprising polyalkylene glycol placed inside a sterile packaging liquid medium comprising an amount of the water soluble polymer component in addition to that present in the contact lens body is used], it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound." *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007). Thus, the burden is on the Examiner to identify and articulate a reason why one of ordinary skill in the art would replace or add a very specific chemical into both the contact

lens AND the packaging solution, other than the general statement: "As such, a skilled artisan would have a high level of expectation of success following the teachings of the references" (pages 5 and 7, Examiner's Answer). Without the motivation to chemically modify the composition of a contact lens AND the packaging solution, the question of "expectation of success" becomes irrelevant. Appellant respectfully submits that a skilled artisan would NOT be motivated to follow the teachings of the cited references, for at least the following reasons.

First, as set forth in the previously submitted Appeal Brief, the need or the problem dictating the inclusion of the same water soluble component in the contact lens body AND in the packaging solution is its migration from the contact lens into the surrounding packaging liquid medium which can result in a decreased concentration of the compound when the contact lens is finally worn. This problem was not previously recognized until identified by the instant application. Thus, the purpose of using the recited compound in both the claimed contact lens and packaging solution in the instant application is unique and not previously appreciated. As the need for including the SAME water soluble component in the contact lens body AND the packaging solution was not recognized until identified by the instant application, there is no motivation for a skilled artisan to combine the teachings of the cited references to come up with the claimed package system.

Second, without a sound scientific reason to implement a certain compound in the contact lens body AND the packaging solution, given the amount of resources and time required in the evaluation and validation of a chemical out of a very long list of available compounds to ensure its efficacy and safety as required by stringent FDA regulations, Appellant submits that "one of ordinary skills in the art could not have combined the claimed elements by known methods" due to the foreseeable difficulties in such an attempt (MPEP§2141(V)).

Third, the Examiner's reliance on the prior art and especially the Krezanoski patent directly contradicts its express teachings of not arbitrarily combining soft contact lenses with commercially available cleaning, storing, and wetting solutions due to unpredictable and often unsafe results.

In view of the foregoing, Appellant respectfully maintains that one of ordinary skill in the art would not be motivated to combine the teachings of the references to come up with the claimed package system. Accordingly, the Examiner failed to establish a prima facie case for

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obviousness, and claim 172 is patentable for at least this reason. As claims 173-178 and 186 depend from claim 172, they are also allowable for at least the same reason.

III. **CONCLUSION**

For the above reasons, claims 172-178 and 186 are believed allowable and reversal of the rejections is respectfully requested.

Respectfully submitted,

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